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Randolf von Oepen

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EXAMINER

HUGHES, ALICIA R

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/015,274	Applicant(s) VON OEPEN, RANDOLF	
	Examiner Alicia R. Hughes	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-13, 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-16 and 19-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-35 are pending. Claims 1-13 and 17-18 are withdrawn from consideration, as they are part of a non-elected invention. Claims 14-16 and 19-35 are the subject of this Office Action.

Claim Rejection - 35 U.S.C. §112.1

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-16 and 19-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Applicant argues that he is entitled to a patent if he has “described an apparatus with *adequate specificity*, so that a person skilled in the art can reproduce the invention, *even if the applicant does not understand why the apparatus or process produces those results*” (Reply to Office Action of 1/22/2007, page 10 of 17, Paragraph 3)(emphasis added). The Office agrees. However, the rejection preferred pursuant to 35 U.S.C. § 112, first paragraph is based on a lack of written description rather than a lack of enablement. Agreeably, applicant does not have to

understand or state scientific principles underlying their invention. However, Applicant must know *what the invention is* to claim possession and be able to communicate that knowledge of what the invention is to the skilled artisan.

Applicant also points to portions of his specification that give examples of restenosis inhibitory agents to bolster his position that the disclosure does not lack proper written description, citing *Regents of the University of California v. Eli Lilly*, 119 F. 3d 1559, 1568 (Fed. Cir. 1997). However, *Regents of the University of California v. Eli Lilly* is distinguishable from the instant case, because a chemical formula for which there is a corresponding core structure, with variable substituents is lacking. While the table presented in the specification lists some inhibitors with identifiable chemistries, these are often listed as examples of broader classes and these examples do differ structurally. Rather, as noted in this Office's previous action, the instant application's reference to a restenosis-inhibiting moiety is inadequate, as the Applicant has not identified a description of each of the restenosis-inhibiting compounds.

As noted previously, claim 14 is drawn to a kit for inhibiting restenosis in a patient vessel where the kit comprises, in pertinent part, a restenosis-inhibiting moiety. The specification is written broadly, simply advising over "[e]xamples of molecular entities useful as growth and/or restenosis inhibitors agents" (Specification, p. 81, lines 23-26 and Table 10, pp. 81-83) and further, defining a restenosis inhibitory agent or moiety as "a molecular entity (i.e., nucleus, atom, ion, molecule, compound, substance, or drug) capable of inhibiting restenosis by a mechanism, ***even if unknown***, distinct from that of emission of radioactivity" (Specification, p. 79, lines 4-8) (Emphasis added). The listing of this non-exacting reference and reference to the

“unknown” is insufficient to meet the written description provision of 35 U.S.C. 112, first paragraph.

In short, the specification is lacking sufficient written description to support the genus disclosed in claim 14, because the restenosis-inhibiting moiety is not sufficiently and completely disclosed. As a matter of law, an adequate written description requires more than a mere statement that the matter claimed is part of the invention accompanied by reference to potential compounds. Disclosure of the compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

Claims 14-16 and 21-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claim 14 is drawn to a kit for inhibiting restenosis in a patient vessel where the kit also comprises, in pertinent part, an intravascular medical device. However, the specification only discloses art to support a single intravascular medical device, a stent. As a result, the specification does not provide a written description useful to any person skilled in the art to which it pertains, or with which it is most nearly connected.

Claims 14 and 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claim 25 is drawn, in pertinent part, to a kit that contains a linker moiety. The specification is written broadly, however, simply advising that the “linker *may* comprise a modified or unmodified biomolecule, an organic molecule, an inorganic molecule, or a combination of biomolecules, organic molecules, or inorganic molecules” (Specification, p. 23, lines 15-18)(Emphasis added). The listing of this non-exacting is insufficient to meet the written description provision of 35 U.S.C. 112, first paragraph. Albeit linker moieties are known by skilled artisans in the chemical arts, generally, the specification should be clear as to what does and does not comprise a linker moiety for purposes of this invention.

In short, the specification is lacking sufficient written description to support the genus disclosed in claim 14, because the linker is not sufficiently and completely disclosed. As a matter of law, an adequate written description requires more than a mere statement that the matter claimed is part of the invention accompanied by reference to potential compounds. Disclosure of the compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

Claim Rejections – 35 U.S.C. §103(a)

The following is a quotation of 35 U.S.C. §103(a), which forms the basis for all obviousness rejections set forth in this office action:

(a) A patent may not be obtained through the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was

made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

For the purpose of examination herein, the pending claims are given their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim should not be read into the claim. *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (claims must be interpreted “in view of the specification” without importing limitations from the specification into the claims unnecessarily). *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969).

Intravascular medical device is interpreted as a stent. Linker moiety is interpreted as comprising a modified or unmodified biomolecule, an organic molecule, an inorganic molecule, or a combination of biomolecules, organic molecules, or inorganic molecules.

Claims 14-16 and 19-23, and 28-35 are rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,871,436 [hereinafter referred to as “Eury”] in view of U.S. Patent No. 5,871,437 [hereinafter referred to as “Alt”] and in further view of U.S. Patent No. 5,873,811 [hereinafter referred to as “Wang et al”].

Applicant argues that: (1) Eury does not teach or suggest a restenosis-inhibiting moiety configured for administration to the patient after implantation of the stent in the vessel; (2) Alt does not overcome this deficiency, because Alt is directed to a stent having a coating that contains a radioactive source of beta emitting properties for irradiation of tissue when the stent is implanted in a patient's vessel and the product containing the radioactive source is configured for coating prior to implantation is not a restenosis-inhibiting moiety configured for

administration to the patient after implantation of the stent; and (3) Wang's adhesive is configured to bond to the vessel wall and not configured to bond to the stent surface, because it does not contain a second member of the specific binding pair capable of binding to the first member as recited in the Applicant's claim 14. The same is refuted based upon the disclosures below.

To the contrary of the Applicant's assertions, as noted prior, Eury teaches a method for providing a pre-selected dosage of radiation to a patient by inserting an expandable stent that is at least partially coated with a chelator, which has a selected covalent binding affinity for a pre-selected radioisotope or a linker moiety (Eury, Col. 4, lines 1-18, Col. 5, lines 24-29 and col. 6, lines 1-11, claims 1-3). Eury also teach that a base layer attached to the radioisotope affixed to the stent, with a linker moiety that is bonded to the base layer (Eury, Col. 6, lines 12-27, claim 4).

Eury also teaches that the stent claimed is "initially provided in a collapsed state and positioned about an inflatable balloon on the distal end of a catheter" (Eury, Col. 3, lines 50-53), and that the most preferable embodiment of his invention is a stainless steel stent, a gold base layer, with α,ω -mercaptoalkylamine as a spacer (or linker), N^1 -(2-hydroxyethyl)-ethylenedramine-N,N, N^1 triacetic acid as a chelator and Ir^{192} as the radioisotope (Eury, Col. 4, lines 57-60).

While Eury does teach the inhibition of restenosis utilizing an expandable stent implanted via a catheter, said stent being at least partially coated with a chelator with an chemical binding affinity for a radioisotope and/or linker moiety, Eury does not teach this embodiment further comprising an agent that can selectively disrupt the binding pair that links the radioactive moiety

to the stent nor the first member of the binding pair, which is affixed to the stent, being immobilized to an expandable film lining the surface of the stent. However, the same is taught by Alt.

Alt teaches an implanted, non-radioactive, expandable metallic or non-metallic stent coated with a biodegradable thin coating, wherein the coating contains multiple layers, including one layer with a radioactive source and a tight binding affinity for the surface of the stent (Col. 6, lines 66-67 and Col. 7, lines 1-4 and lines 24-27, Col. 8, lines 61-63). The layer closest to the stent surface contains the radioactive source, such as a radioactive phosphorus isotope *that may be coupled to a nonresorbable and readily excretable substance, like insulin* (Alt, Col. 8, lines 30-36), and *the second layer incorporates an anti-coagulant substance to inhibit early thrombus formation (Col. 4, lines 65-67), such as prostaglandin derivatives, anti-adhesive peptides, etc.* (Col. 3, lines 1-13). Finally, Alt discloses the incorporation of anti-proliferation substances into the coating carrier of the stent, noting that substances such as tamoxifen and other cytostatic drugs directly interfere with hyperplasia in a manner that enables them to slow or prevent restenosis, particularly when there is a slow release of the coating of the stent (Col. 3, lines 14-26).) Notably, these are, based on the disclosure in Applicant's specification, for all intents and purposes, restenosis-inhibiting moieties configured for administration to the patient after implantation of the stent.

Wang et al disclose teachings pertinent to the present invention not taught by Eury or Alt. Wang et al teach a method and composition for use in inhibiting restenosis comprising an adhesive that contains biodegradable molecules capable of body adsorption over time (Col. 8, lines 8-12). The adhesive composition contains a radioactive material that is chemically bonded

to, and therefore, a part of the adhesive (Col. 8, lines 13-16), which is on the stent surface. The radioactive material can be Phosphorus 32, Yttrium 90, Iodine 125, Iridium 192 and mixtures of any or all of these (Col. 8, lines 17-21). In addition to containing radioactive material, the adhesive also contains polymeric material (Col. 8, lines 22-24). In addition to being chemically bonded to the adhesive, the radioactive material bonds to the polymeric material (Col. 8, lines 22-24). Wang et al also teach administration of the adhesive composition by catheter and the placement of a stent by the same means (Col. 7, lines 24-27 and Col. 8, lines 6-7). Wang et al also teach that chelation can be used to bind radioactive materials, and that “chemically bonded pendent phosphate groups having P-32 are within the scope of the invention” (Col. 6, lines 48-50 and 54-56).

One of ordinary skill in the art would be motivated to combine the teachings of Eury, Alt, and Wang, because each is related to the inhibition of restenosis utilizing stents and/or catheters. And those of ordinary skill in the art have long known the effective interrelationship of stent-catheter systems to treat stenosis. See generally, U.S. Patent No. 5,059,166 [hereinafter referred to as “Fischell et al”] and the references cited therein.

in light of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art that a kit which contained a stent made radioactive subsequent to implant in a patient vessel via catheter transportation, wherein the stent contained a radioactive component with a chelator containing the member of a binding pair with the chemical affinity to bind its other member, which is bonded to a restenosis-inhibiting moiety would possess the capability to inhibit restenosis.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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/Alicia R. Hughes/
Examiner, Art Unit 1614

/Raymond J Henley III/
Primary Examiner, Art Unit 1614